Attachment #4: Statement of Work

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to support the Central Institutional Review Board Initiative.

TASK 1: Initial Transition

A. Upon contract award, the draft Initial Transition plan, submitted with the Contractor's proposal will be revised, as needed. Upon approval of the plan by the Contracting Officer's Representative (COR), the Transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities and materials within 60-days of contract award. The Initial Transition Plan shall delineate the following: transition activities to be undertaken; timelines for the completion for each transition activity; and staff to be assigned. The Contractor shall deliver a Draft Initial Transition Plan to the NCI COR and Contracting Officer for review and approval within seven (7) days of contract award and a Final Initial Transition Plan no later than one (1) week after receipt of Government comments. Concerns anticipated or encountered shall be immediately communicated to the COR and an approved resolution pursued.

TASK 2: Manage and provide administrative and regulatory support for three Central Institutional Review Boards (adult phase 3 and large phase 2 trials; early 1 and 2 phase trials; and pediatric trials)

A. Manage and provide administrative and regulatory support for scheduled and occasional unscheduled, ad-hoc CIRB meetings for each CIRB, including all administrative tasks involved in the preparation, conduct, and follow-up of meeting actions (includes managing expedited review) per the CIRB SOPs (https://ncicirb.org/cirb/default.action). These tasks include, but are not limited to, the following:

1. Ensure that each CIRB maintains a membership with adequate expertise to review their assigned NCI-sponsored trials and has a Chair and Co-Chair with IRB and/or CIRB experience.

2. Receipt of all CIRB-required documentation from the NCI's Cancer Therapy Evaluation Program's (CTEP) Protocol Information Office (PIO), the Study Chair, coordinating groups, networks, or programs via the mechanism that will be used by them to supply study-related materials to the CIRB for review.

3. Advise the CIRB during their review of consent forms regarding the compatibility of the consent form with the regulations and the

current NCI Consent Form Template (http://ctep.cancer.gov/protocolDevelopment/informed_consent.htm)

4. Appropriately assign reviewers for each review to be conducted, including initial review, continuing review, amendment review, etc.

5. In advance of the CIRB meeting, inform the study-specific Study Chair, or designee, of the date and time of their study's review for each item on the meeting agenda. Also inform the CTEP disease therapeutic leads, and/or lead drug monitors, or their designees, of the date and time for initial reviews and group responses to initial reviews that are on the meeting agenda.

6. Arrange for a conference call line for each regularly scheduled and ad hoc CIRB meeting.

7. Connect the Study Chair and NCI study leads into the CIRB meeting when the CIRB Chair has indicated the CIRB is ready for the Study Chair and CTEP to join the conference call.

8. Arrange for Adverse Events to be reviewed per the CIRB SOPs (https://ncicirb.org/cirb/default.action). Assign reviewers for Serious Adverse Events (SAE) documents that are received from CTEP or the coordinating groups, forward those documents to the SAE subcommittee reviewer(s), and collect their recommendations, when the CIRB SOPs indicate that SAEs require review. Confirm that the reviewer's recommendations for language changes to the consent form are accurate then ensure that the reviewer's recommendations are posted on ePanel® for the next meeting of the appropriate CIRB.

9. Coordinate, prepare and distribute agendas for all meetings.

10. Coordinate, prepare, and distribute meeting packets including agenda and related review materials to CIRB members.

11. Upload meeting documents to ePanel® the CIRB panel protocol review, collaboration and meeting management tool at least eight business days prior to the CIRB meeting (see Task 7).

12. Advise the CIRB during their review of consent forms regarding the compatibility of CIRB-suggested changes with the regulations and the current NCI Consent Form Template.

13. Obtain CIRB approval for minutes of regular CIRB meetings, ad-hoc CIRB meetings, ad-hoc SAE Subcommittee meetings, and ad hoc COI Subcommittee meetings. Minutes shall be prepared using the established minutes template and submitted to the CIRB for review via CIRB panel protocol review and meeting management tool (to be provided by the NCI) at least 3 business days prior to the next CIRB meeting at which time

they will receive a vote to approve. Minutes from ad hoc meetings will be prepared and submitted to the members for a vote via email within 7 business days of the ad-hoc meeting.

14. Record attendance and completion of primary reviewer assignments per CIRB member; manage member's conflict of interest, recusal, and meeting quorum issues per the CIRB SOPs prior to and during all meetings

15. Prepare minutes of ad-hoc conference calls in which the CIRB Chair participates and forward those minutes for review by the Chair and NCI. Minutes shall include salient points of discussion and highlight any action items.

16. Prepare all correspondence related to CIRB meeting review outcomes, including, but not limited to, drafting outcome letters and sending the drafted letters to the Chair for signature(s), then distributing the letters to appropriate Study Chairs, copying additional relevant staff per their request or CIRB SOPs. Approval letters shall be distributed to Study Chairs via email within three days with the rest of the outcome letters distributed within seven days.

17. Communicate with the Chair, CIRB members, and CIRB panel protocol review and meeting management tool (to be provided by the NCI) staff via telephone and electronic mail, as necessary, to ensure smooth operations.

18. Distribute meeting honoraria for each meeting attended to CIRB members in the amount of $400, Vice Chairs in the amount of $700, and Chairs in the amount of $1,000.

B. Post all CIRB-reviewed study-specific information on the CIRB section of the CTSU website as closely as possible to the time the study or reviewed material is posted by the coordinating group.

C. Maintain and update annually the CIRB SOPs guiding CIRB and the CIRB Initiative Operations Office functions. Individual SOPs for new or revised processes may be drafted/updated more frequently as required. The Contractor shall ensure that all CIRB SOPs are in compliance with Federal laws and regulations, and that all administrative activities and CIRB actions are in compliance with the CIRB SOPs.

D. Plan, organize and conduct orientation education programs for new CIRB members; new CIRB Chairs and Vice Chairs; and new Local Context Subcommittee members.

E. Provide continuing education activities for CIRB members which may include and are not limited to: brief monthly presentations during CIRB

meetings, presentations during the CIRB Member Education Day webinar, etc.

F. Identify CIRB members' educational needs related to their service as a CIRB member which may be addressed during the annual CIRB Member Education Day webinar. The Contractor shall develop and maintain education records for each CIRB member.

G. Provide support to the NCI in identifying and selecting CIRB members, including tracking tenure and categories of CIRB Board members in the Member Activity Tracking Database. Maintain a listing of potential/future appointees.

H. Gather short biosketches for each CIRB member and post on the CIRB website. If necessary, assist CIRB members with preparation of the biosketches or prepare the biosketch for them. Biosketches should be posted on the CIRB website within four weeks of the member's first CIRB meeting.

I. Purchase and hold professional liability insurance for CIRB members without gaps in coverage at time of renewal.

J. Update annually the instructional handbook for Study Chairs, coordinating group staff, and PIO staff to provide information regarding their interactions with and responsibilities to the NCI CIRB.

TASK 3: <u>Establish and support a new CIRB for review of DCP trials</u>

A. Establish and provide support for a 4th CIRB to review DCP trials within 120 days of contract award as delineated in Task 2.

B. Upon contract award, the draft DCP CIRB plan, submitted with the Contractor's proposal will be revised as necessary and submitted to the COR for review and approval within 45 days after contract award. The final DCP CIRB plan shall be followed to ensure an orderly, secure, efficient, and expedient establishment of the DCP CIRB.

C. The requirements to support the DCP CIRB shall be consistent to those of the other 3 boards identified in Task 2. Minimal customization of procedures, policies, system and infrastructure is allowable to meet any unique requirements of the DCP CIRB.

TASK 4: <u>Manage and provide administrative and regulatory support for CIRB review of enrolled institution's local context considerations</u>

A. Revise the Worksheets per the CIRB SOP's (https://ncicirb.org/cirb/default.action) to gather information about local context considerations, as necessary.

B. Incorporate suggestions from users, when feasible, to enhance the ease of use and user satisfaction of the forms

C. When a need is identified by the contractor, institution staff, or NCI staff, develop additional on-line forms to facilitate efficient reporting to the CIRB

D. Improve current materials or develop new materials, as needed, to assist staff from Signatory Institutions to understand CIRB policies and procedures, including completion of the required Worksheets and forms.

E. Maintain an adequate amount of qualified CIRB Local Context Committee reviewers for each CIRB

1. Provide thorough process orientation for CIRB reviewers prior to assigning this type of review.

2. Track their review times, including providing reminders to complete their reviews in a timely manner

F. Track critical activity milestones, including but not limited to:

1. Dates of receipt, length of internal review, length of CIRB review of the three Worksheets being used to establish local context considerations for the CIRB (Annual Institution Worksheet About Local Context, Annual Principal Investigator Worksheet About Local Context, and Study-Specific Worksheet About Local Context) plus all other on-line per the CIRB SOP's (https://ncicirb.org/cirb/default.action).

2. The final CIRB review outcome and date of each Worksheet or form.

3. The date the final outcome for each was provided to the Signatory Institution.

4. The date the final outcome for each was reported to the CIRB.

5. Name of internal reviewer for each Worksheet or form.

6. Name of CIRB reviewer for each Worksheet or form.

G. Maintain a tracking log of correspondence, types of correspondence including emails, phone calls, written correspondence, between Signatory Institution staff and the CIRB Operations Office and between the Signatory Institution staff and the CIRB reviewer, including but not limited to:

1. Name of Signatory Institution staff.

2. Name of CIRB Operations Office staff and/or CIRB reviewer.
3. Date, time, and type of correspondence.

4. Topic of correspondence.

5. Resolution.

H. Maintain a tracking log of Signatory Institution Status, including but not limited to the following:

1. Complete list of Signatory Institutions enrolled in Initiative, including number of affiliates and components for each.

2. Identify Signatory Institutions and number of their affiliates and components who participated in Pilot Study.

3. Identify Signatory Institutions and number of their affiliates and components who withdraw from CIRB Initiative, include reason for withdrawal.

I. Track number of studies opened by each Signatory Institution as follows:

1. Signatory Institution name.

2. Institution Code#.

3. Study ID#.

4. Date reported.

TASK 5: **<u>Enroll new institutions to the CIRB Initiative</u>**

A. Track all enrollment activities including date, method, and content of interactions with institution staff then provide an activity report on a monthly basis to the COR. Track and facilitate an interested institution's progress through the enrollment process until they have opened a new study.

B. Provide a Helpdesk with knowledgeable staff to answer any questions and concerns as they are presented to the Helpdesk. The Helpdesk shall consist of telephone, voicemail, and electronic mail capabilities. The Helpdesk shall be staffed and the phone answered by a person between 8:00AM and 4:00PM, ET, with voice-mail provided during non-working hours.

C. Maintain an interaction tracking log, of phone calls and electronic mailings received through the Helpdesk, detailing and categorizing requests and

their related responses; provide a summary of the tracking log as requested by the COR.

D. Develop and maintain CIRB SOPs for the integration of new institutions into the CIRB Initiative's processes and database.

E. Revise and update the instructional handbook for local institution staff annually and as necessary.

F. Provide a sample SOP on the CIRB public website for incorporating the CIRB into an institution's existing processes.

G. Enhance existing and/or develop new educational materials for recruitment, enrollment and facilitation of local site integration into the Initiative.

H. Provide educational support to the NCTN and ETCTN membership regarding the CIRB initiative, such as:

1. Maintaining, updating, and/or developing, as necessary, text for the public side of the website.

2. Develop and give presentations about the CIRB at national oncology conferences as requested by the COR.

3. Setting up and staffing exhibit booths/tables at national oncology conferences as requested by the COR.

4. Assist the NCI staff with identifying local institutional staff, who can communicate CIRB user-experience to prospective enrollee institutions.

5. Conduct post-conference/presentation follow-up as needed.

TASK 6: **<u>Manage and support new and already enrolled institutions</u>**

A. Provide continuing support to enrolled institutions as they continue to interface with the CIRB, including the following:

1. Create and distribute electronic updates of website postings to all email addresses of enrolled institutions twice a month.

2. Provide education on new procedures to institution staff and investigators in a timely manner.

3. Develop and maintain reports that include all or some of the following data points: names and contact information of enrolled signatory institutions and their components and

affiliates.

B. Develop and maintain reports that include all or some of the following data points captured during submission of the Study-Specific Worksheet: Study ID number and name, Signatory Institution name, Signatory Institution's Principal Investigator name. and contact information.

C. Develop, maintain and revise, as necessary, SOPs for managing and supporting current and newly enrolled local institutions.

D. Coordinate the interface between the CIRB and the Cancer Trials Support Unit to assure smooth functioning of the regulatory requirements for enrolling patients on trials. This will include, but not be limited to, the following:

1. Supplying information regarding CIRB institutions that have opened a study

2. Documenting the network of affiliate and component institutions of a Signatory Institution

3. Develop and maintain a user-friendly annual renewal process to confirm an institution's continued participation in the CIRB Initiative.

TASK 7: <u>Provide IT software and support for CIRB operations</u>.

A. Maintain and enhance, as necessary, the CIRB system's for reporting and tracking study-related activity as well as tracking local site activity, to include, but not be limited to, the following data:

1. <u>Studies</u>

a. Group protocol ID number.
b. Study title with ability to query key words.
c. Name of Study Chair.
d. Contact information of the Study Chair.
e. NCI Protocol Version Date.
f. All CIRB actions (with dates) for each study.
   i. Initial review with immediate, intermediate and final outcomes, when applicable.
   ii. Amendment review with immediate, intermediate and final outcomes, when applicable.

iii. Adverse event review with immediate, intermediate and final outcomes, when applicable.
iv. Continuing review with immediate, intermediate and final outcomes, when applicable.
v. Reviews of miscellaneous documents, such as recruitment materials, including outcomes of all reviews, when applicable.

2. Participating Institutions

a. Signatory Institution profile
i. Name.
ii. Contact information for research staff.
iii. Date of enrollment.
iv. Description (NCI-designated cancer center, Community Clinical Oncology Program (CCOP), academic or community site).
v. Log of studies opened, including local principal investigator name.
vi. Local IRB(s) on the signatory's assurance
b. Contact information
c. Federal-Wide Assurance number.
d. IRB Organization Number.

3. Maintain a site/principal investigator log that can be queried by criteria or keywords such as state, city, network affiliation, or by specific study.

B. Maintain, and enhance the links between the CIRB database and other related activities, such as the CTSU regulatory database, DCP and CTEP databases. To support integration with other NCI systems the contractor shall participate, as needed, in joint informatics development efforts, which shall include software development, database integration, application integration, and implementation and training of shared information management resources to facilitate system harmonization and interoperability.

C. Maintain the public CIRB website, as needed, including, but not limited to, the following tasks:

1. Host the website.

2. Ensure the website meets Federal requirements for accessibility.

3. Ensure navigational ease for website users using current technology and proven, successful website design.

4. Develop methods and processes to assure that the website is meeting the needs of the NCI and Oncology community.

5. Coordinate linkages between the CIRB website and other NCI websites, for maximized efficiency and limited content duplication.

6. Ensure internal continuity and quality control, and demonstrate how revisions to any webpage will be applied to similar information that might appear on other pages throughout the websites.

7. Updating the CIRB website to incorporate timely dissemination of information, as necessary or when specifically requested by the Contracting Officer Representative.

8. Update the 'Frequently Asked Questions' section of the website as well as the look and feel of the public side of the website, as necessary, to provide a comprehensive and instructional tool for stakeholders as well as those interested in the CIRB Initiative.

D. The CTSU provides the website framework for the CIRB including but not limited to user access, formatting and security. The CIRB Contractor shall maintain CIRB content on CTSU website, as needed, including, but not limited to, the following tasks:

1. Develop methods and processes to assure that the website is meeting the needs of the NCI and CIRB membership.

2. Coordinate linkages between the CIRB systems and the CTSU Website.

3. Coordinate with the CTSU contractor to ensure CIRB technical, regulatory and operational needs are met.

4. Ensure internal continuity and quality control, of CIRB content.

5. Posting all CIRB documents and hyperlinks related to study review and activity.

6. Updating the CIRB content on the CTSU Website to incorporate timely dissemination of information, as necessary or when specifically requested by the Contracting Officer Representative.

E. The Contractor shall develop, maintain and follow an IT security and risk mitigation plan consistent with NIST requirements (http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/nist80

0-30.pdf). This plan will be reviewed and approved by the COR and include the following:

1. Ensure all CIRB security plans and processes are independently Certified and Accredited (C&A) and filed with the NCI Chief Information Officer.

2. Provide a proposed maintenance schedule for regular system maintenance to include downtime for maintenance/updates with the least impact to the operations of the systems. The Government anticipates peak hours for all systems to be weekdays from 8:00 AM – 8:00 PM Eastern Standard Time (EST).

3. Provide a detailed back-up plan for system failure to include plans for testing the disaster recovery plan at least twice per year.

4. Provide geographically separate fail-over capability for CIRB systems that shall ensure CIRB critical applications are operational within 4 hours and be fully operational within 24 hours of a natural disaster.

5. Data Transfer of PII or sensitive information to the NCI is to be encrypted.

F. IRBManager:

1. Obtain IRBManager© license, including hosting and maintenance of both a testing and production server environment, for the first 18 months of the contract. The NCI will make other arrangements to maintain the IRBManager© license for the remainder of the contract.

2. The Contractor shall procure custom configuration maintenance and development of IRB Manager©.

3. Maintain the functional data transfer between IRBManager and other NCI IT systems.

4. Enhance/update IRBManager and other CIRB databases to address evolving regulatory and administrative needs of the CIRB, and to maximize the efficiency and effectiveness of CIRB operations.

G. CIRB System for Enrollment

1. The Contractor shall maintain and enhance an automated system to capture, maintain and track CIRB participating site and individual information.

2. The Contractor shall procure a license and provide services for Advantage EDC.

3. Within 6-months of contract award the Contractor shall provide an analysis to determine the optimal methodology to track CIRB participating site and individual information. The analysis shall compare continued use of Advantage EDC, a Commercial Off-The-Shelf (COTS) product or other appropriate solutions.

    a. Within 30-days of receipt of the analysis the COR will either request additional data to support the analysis and/or provide the contractor a decision regarding how to proceed with long term IT support for CIRB Enrollment management.

    b. Based on the COR decision the contractor shall have a long term IT solution to maintain and track CIRB participating site and person information in place within 18-months of contract award.

    c. Maintain and enhance the approved solution.

H. ePanel

1. ePanel is a protocol review, collaboration and CIRB meeting support tool.

2. Within 6-months of contract award the Contractor shall provide an analysis to determine the optimal methodology to support protocol review, collaboration and CIRB meetings. The analysis shall compare continued use of ePanel®, Commercial Off-The-Shelf (COTS) products, or other appropriate solutions.

    a. Within 30-days of receipt of the analysis the COR will either request additional data to support the analysis and/or provide the contractor a decision regarding how to proceed.

    b. Based on the COR decision the Contractor shall have a long term solution to support protocol review and CIRB meetings in place within 18-months of contract award.

    c. Maintain and enhance the approved solution.

I. Software development, testing and maintenance for current and future CIRB I.T. infrastructure.

1. Implement the best practice for software and system development, testing, maintenance, and IT governance consistent with the Department of Health and Human Services (HHS)

Enterprise Performance Life Cycle (EPLC) practices to enhance Information Technology (IT) governance (http://www.hhs.gov/ocio/eplc/index.html).

2. Provide an effective systems configuration management process that is consistent with the guidelines set forth by NCI's Center for Bioinformatics (http://ncicb.nci.nih.gov/) and National Cancer Informatics Program.

3. All new CIRB custom built IT applications must be developed utilizing open source code. All versions/releases of all systems documentation (user and technical) as well as source code for open source systems and system components shall be stored in the NCI repository.

4. Upgrade and maintain the CIRB applications to ensure they are current with evolving technology, regulatory and operational requirements.

5. Enhance functionality of CIRB applications to improve efficiency address operational gaps, and address new requirements.

6. Collaborate with IT and operational staff from other the NCI IT contractors to identify system improvements that will translate into operational efficiency, elimination of redundant systems, and/or cost savings across the NCI IT portfolio.

7. Provide and implement a plan to archive CIRB IT systems that no longer adequately support CIRB operations.

8. All applications shall be developed and/or maintained to reduce unnecessary data redundancy and promote system efficiency and high performance.

9. Develop and provide a Master Project Plan that includes a brief description of each project. The Master Project Plan shall be reviewed and if needed revised at least once every 6 months.

10. Application Specific Project Plan – Every new development project shall have a Project Plan that details the process the development team will follow, organizes and coordinates the work, and estimates and allocates cost and schedule for each sub-process/phase. The Application-Specific Project Plan shall be reviewed and revised as needed. As the project progresses revised budget and timeline estimates shall be included. For reference, the original estimates and actual expenses shall also be included.

11. If the Contractor is considering a COTS product for integration, the Contractor shall provide assessment of COTS products prior to procurement, customization, integration, and/or implementation.

J. I.T. Infrastructure Change Management

1. The Contractor shall modify and implement a formal process for IT change management. This process shall include the development of a plan which shall include provisions for collecting, tracking, assessment, approval and implementation of change requests. A separate change management process shall be developed for projects in-development and those that are 'active' or resulting from system integration and/or harmonization.

2. The CORs must approve any change to an active application that requires an estimated level of effort of 40 hours or more to complete.

a. The Contractor shall provide impact analysis for all change requests including costs, personnel, labor hours and affected CIRB applications.

3. The Contractor shall assure that all relevant stakeholders (end-users, CORs, Branch Chiefs) are represented in the change management process. The Contractor shall review changes with all relevant stakeholders to ensure agreed upon requirements and specifications are met.

4. The Contractor shall notify all relevant stakeholders prior to implementation of any changes to CIRB software.

TASK 8: C<u>ommunicate with NCI and stakeholders regarding all aspects of the CIRB Initiative</u>.

A. Provide organized and detailed project management leadership and support of the following activities:

1. Meet with the NCI team on a monthly basis to provide status reports for every aspect of the CIRB Initiative. Generate the agenda and minutes for all Contractor- NCI status meetings, providing project calendars with deliverable dates and development timelines.

2. Meet with the NCI team weekly as needed for project meetings to resolve challenges, develop new procedures, when necessary. Generate the agenda and minutes for all Contractor-NCI project meetings, providing project calendars with deliverable dates and development timelines.

3. Provide monthly data updates (to be included as part of the monthly progress report), that inform the NCI on all aspects of the CIRB Initiative.

4. Develop and provide a PowerPoint slide set, suitable for presentation at major Oncology conferences or NCI meetings, that summarizes all areas of the CIRB initiative. The slide set shall be updated and revised on a monthly basis to assure currency.

B. Maintain effective communications with the Cooperative Groups or other network Operations Offices, including participating in standing meetings and teleconferences, developing, maintaining and updating instructional handbooks and developing other communications methods, as needed.

C. Maintain effective communications with relevant CTEP Contractors/Branches/Initiatives, such as the PIO and CTSU. This includes participation in standing meetings/teleconferences, developing, maintaining communications methods, etc.

D. Assist COR with maintaining OMB clearance for CIRB forms.

E. Contractor management shall be available to meet frequently and/or on short notice (within 48 hours of request from the NCI COR), with CTEP Program staff, when requested.

TASK 9: **Implement and manage an Initiative-wide Quality Improvement Plan.**

A. Identify challenges, risks and opportunities for the CIRB initiative. Recommend procedures, processes and mechanisms (i.e., technology) to facilitate, streamline, or improve CIRB operations, in order to improve the efficiency and effectiveness of operations.

B. Develop (in collaboration with the COR), implement and manage a Quality Improvement Plan for all aspects of the Initiative. Identify Quality Improvement indicators that need to be monitored, monitor those indicators and report results to the COR.

C. Seek periodic feedback from all CIRB stakeholders, including local IRBs and research staff, CTEP's PIO, and Cooperative Group staff, to ascertain satisfaction with the CIRB Initiative as well as to gather their suggestions for potential process improvements. The Contractor shall then provide this feedback, from all stakeholders that submitted feedback, to the NCI.

TASK 10: Maintain AAHRPP Accreditation per AAHRPP requirements

A. Provide management and support for maintaining Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) accreditation.

B. Provide monthly accreditation status reports as an inclusion in the status meeting and the monthly Progress Report.

C. Send one staff member to the annual AAHRPP conference to gather accreditation updates and provide this information at an update meeting including NCI and relevant staff.

Optional Task 1: Phase-Out Transition

A. Within 6-months prior to the completion date of the contract, the Contractor shall develop and submit a draft phase-out transition plan which will describe the Contractor's strategy for transferring work from this contract to a successor contract, in the event a final transition would be required. The Final Transition Plan shall be submitted to the Government no later than four (4) months prior to the completion date of the contract. The plan must include a system for transfer of policies and procedures; transfer of relevant files, records, materials, and data; all source code and object code developed, modified, and/or enhanced under the contract; transition of all activities, and transition of all CTSU-Enterprise applications, as appropriate. All source code and object code shall be developed on or before the contract expiration date. The draft phase-out transition plan will be revised, if necessary. The approved final transition plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities by the contract completion date.

Optional Task 2: Establish and support additional CIRB(s)

In the event the NCI identifies the need for one or more additional CIRBs to support current (Late, Early or Prevention) or new focus areas the Contractor shall:

A. Identify and recommend procedures, processes and mechanisms (i.e., technology) to facilitate, streamline, or improve CIRB operations, in order to improve the efficiency and effectiveness of operations, to support this task as required by the Statement of Work.

B. Develop a plan to establish a CIRB to review the specified trials to be determined (TBD). This CIRB will follow the same CIRB SOPs as the existing CIRBs.

C. Nominate CIRB members with adequate expertise to review TBD trials. Final membership list is due to COR 6 weeks prior to first meeting of this CIRB.

D. Arrange for each CIRB member to be oriented to the CIRB and CIRB panel protocol review and meeting management tool (to be provided by the NCI) per their role at least one week prior to the first CIRB meeting.

E. Modify existing CIRB SOPs and technology to support the new CIRB, including restricting website access to appropriate DCP investigators.

F. Orient NCI contact person to CIRB processes and procedures.

G. Provide similar support for the CIRB and members as listed in Task 2 – 10.

* All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible".

Acronyms/Definitions

A listing of acronyms and definitions used throughout the Statement of Work may be found below:

AAHRPP: Association for the Accreditation of Human Research Protection Programs, Inc.

ACOSOG: The acronym for the NCI-sponsored Cooperative Group named the American College of Surgeons Oncology Group

AdEERS: Adverse Event Expedited Reporting System – system used to report side effects occurring on NCI-sponsored clinical trials

AD-HOC CIRB MEETING: A CIRB meeting with an agenda of less than an hour that falls outside of the regularly scheduled meetings. An ad-hoc CIRB meeting may be called to address any urgent issue for which full-board review is required and the next scheduled CIRB meeting will not occur within seven or more business days..

Adult CIRB – Early Phase Emphasis: The NCI CIRB reviewing adult phase 0, 1, 2, and pilot clinical trials. The Adult CIRB – Late Phase Emphasis meets twice a month.

Adult CIRB – Late Phase Emphasis: The NCI CIRB reviewing adult phase 3 and large phase 2 clinical trials. The Adult CIRB – Late Phase Emphasis meets twice a month.

Annual Principal Investigator Worksheet About Local Context: When completed, this Worksheet informs the CIRB about local context considerations pertaining to the Principal Investigator's conduct of research at the institution. This Worksheet is updated at least annually.

Annual Signatory Institution Worksheet About Local Context: When completed, this Worksheet informs the CIRB about local context considerations pertaining to the Signatory Institution. This Worksheet is updated at least annually.

ASCO: American Society of Clinical Oncology

ASSIGNMENT: The naming of a CIRB member responsible for performing a review.

CaBIG: Cancer and BioInformatics Grid – an initiative sponsored by the NCI Center for Bioinformatics to develop informatics standards and tools that can help advance both basic and clinical cancer knowledge.

CaDSR: Cancer Data Standards Repository – a storehouse maintained on the web by NCI for data terms for both clinical and basic science projects

CALGB: The acronym for the NCI-sponsored Cooperative Group named Cancer and Leukemia Group B

CAT: Complete Audit Tracker is the database developed to track internal audits of operations

CCOP: Community Clinical Oncology Program

CHAD: CIRB Helpdesk Application Database

CIRB: Central Institutional Review Board – a centralized IRB review process for NCI-sponsored trials

CIRB Initiative Operations Office: this term refers to the Contractor's staff who complete the tasks as listed in the in the Statement of Work. For CIRB correspondence, public meetings, and on the CIRB website, this term is preferred over using the contractor's company name.

CIRB Website: URL is www.ncicirb.org

Coordinating Group: The entity responsible for conducting an NCI-sponsored clinical trial.

COR: Contracting Officer Representative

CSE: CIRB System for Enrollment is the database used for tracking institution demographic and personnel information.

CTCAE: Common Terminology Criteria for Adverse Events – criteria that permit uniform reporting of side effects occurring on NCI-sponsored trials.

CTEP: Cancer Therapy Evaluation Program

CTEP Disease Therapeutic Lead: this person is the Clinical Investigations Branch, CTEP, staff member responsible for oversight of a specific cancer disease.

CTEP Lead Drug Monitor: this person is the Investigational Drug Branch, CTEP, staff member responsible for oversight of a specific CTEP-IND agent.

CTES: Clinical Trials Enterprise System – the enterprise consists of a series of interconnected informatics tools used by CTEP and its extramural investigators to manage, report, and coordinate CTEP-sponsored clinical trials

CTMB: Clinical Trials Monitoring Branch

CTSU: Cancer Trials Support Unit

DCP: Division of Cancer Prevention

DCTD: Division of Cancer Treatment and Diagnosis

Early Phase Clinical Trials: Phase 0, 1, and 2 clinical trials

ECOG: The acronym for the NCI-sponsored Cooperative Group named Eastern Cooperative Oncology Group

FWA: Federalwide Assurance

GOG: The acronym for the NCI-sponsored Cooperative Group named Gynecologic Oncology Group

IAM: Identity Account Management

ICH: International Committee on Harmonization – a group of countries including the U.S.A. that met and worked in committee to provide common regulatory guidelines for clinical trials

Institution Primary Contact: The person identified by an Institution who serves as the point person for CIRB correspondence.

IRB: Institutional Review Board

IRBManager: software used as repository for regulatory files and mechanism for institution staff to submit worksheets

MAT Database: Membership Attendance and Tracking database tracks each member's attendance and review completion as well as serving as a resource for storing names of interested potential members and retired members.

NCCTG: The acronym for the NCI-sponsored Cooperative Group named North Central Cancer Treatment Group

NCI: National Cancer Institute

NCIC: The acronym for the Canadian-sponsored Cooperative Group named National Cancer Institute of Canada who partners with NCI on certain trials

NSABP: The acronym for the NCI-sponsored Cooperative Group named National

NCTN: National Clinical Trials Network

Pediatric CIRB: The NCI CIRB reviewing pediatric clinical trials of all phases. The Pediatric CIRB meets monthly.

PIO: Protocol Information Office - The CTEP Office responsible for transmitting approved study-specific documents to and from the NCI CIRB.

QA/QC: Quality Assurance/Quality Control

QOL: Quality of Life

RSS: Regulatory Support System

RTOG: The acronym for the NCI-sponsored Cooperative Group named Radiation Therapy Oncology Group

SPORES: Specialized Programs of Research Excellence

STUDY CHAIR: The individual taking responsibility of the overall conduct of the study on a national scale.

Study-Specific Worksheet About Local Context: When completed, this Worksheet informs the CIRB about local context considerations pertaining to a specific study that the Principal Investigator requests to be open at the institution.

SWOG: The acronym for the NCI-sponsored Cooperative Group named Southwest Oncology Group.